



5276 '00 NOV 16 P3:53

October 23, 2000

Honorable Donna Shalala:
Secretary of Health and Human Services
200 Independence Ave. S. W. Room 615F
Washington, D. C. 20201

Dear Secretary Shalala,

I am a small business owner in Akron, Ohio, providing hearing health care services to the area's hearing impaired. I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing health care and reduce access to hearing health care providers. Please take the time to consider the impact of this proposed hearing aid rule on the nation's hearing-impaired and on the nation's small business hearing health care providers, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Hearing health care providers like me have been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new Administration, FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like me from the market place. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

As you may have seen, the AARP recently published a Consumer Guide to Hearing Aids which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20 percent of those who need a hearing aid have one." Please don't let the FDA erect unwarranted barriers to this safe and effective medical device.

Please don't let the FDA publish its proposed hearing aid rule.

Sincerely,

Diane McClusky, Owner
Miracle-Ear Hearing Aid Centers
Sears/Rolling Acres Mall
Akron, Ohio 44320

93N 0372

Sears Rolling Acres Mall
Miracle-Ear Center
Sears Rolling Acres Mall
2400 Romig Road
Akron, Ohio 44320
(330) 848-7508

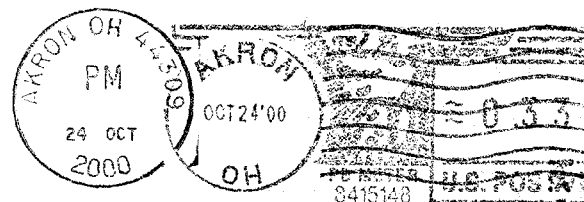
Sears Chapel Hill Mall
Miracle-Ear Center
Sears Chapel Hill
10 Chapel Hill Mall
Akron, Ohio 44310
(330) 633-8141

C4887
Sears Belden Village
Miracle-Ear Center
Belden Village Mall
4100 Belden Village
Canton, Ohio 44718
(330) 966-3281



Miracle-Ear®
A Bausch & Lomb Company

Sears Rolling Acres Mall
2400 Romig Road
Akron, Ohio 44320



Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Ave., S. W.
Room 615F
Washington, D. C. 20201

